

MAIL STOP AMENDMENT

**PATENT
7393/84301**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	VAN HOECKE et al.	Confirmation:	2645
Serial No.:	10/528,167	Art Unit:	1794
Filed:	April 5, 2005	Examiner:	C. Sayala
For:	Composition for replacing milk powder		

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22314

April 10, 2009

Sir:

The following is responsive to the Office Action mailed January 30, 2009.

Applicants traverse the rejection of claims 1-18 under 35 U.S.C. §103(a) as being unpatentable over WO 00/48474 taken with Orban (U.S. 4,054,677) **and** Meheus et al. (U.S. 6,096,353), which combination is taken in view of Ernster (U.S. 4,973,488) and further in view of Armbruster et al. (U.S. 3,849,194) and the Branen et al. article.

The present invention relates to a composition comprising cereal proteins, preferably hydrolyzed wheat gluten and maltodextrin with a DE of 3-10, and preferably a DE of 5, which is chosen such that the amino acids can be added in liquid form and such that salt overloads, and specifically to overcome the overload of chloro atoms which, as discussed on page 7 of the present

specification, might imbalance the nutritional value of a feed composition. As also discussed, the most suitable and efficient drying process involves applying a ring dryer.

Combining hydrolyzed wheat protein and maltodextrin, each having a certain degree of hydrolysis (DH for proteins and DE for maltodextrin), allows it to be combined with free amino acids in liquid form, and Applicants discovered a ring dryer is a most effective/efficient drying method for this combination of products.

It is not a matter of knowing that wheat gluten, maltodextrin, and free liquid amino acid might be – *arguendo* – available individually, or could be applied in a composition suitable for calf milk replacement. The statutory command reads “would have been” **not** “could have.”

The combination of the features in the claims, such as, hydrolyzed wheat gluten, maltodextrin, and free liquid amino acid, shows Applicants’ claimed inventive contribution to the art would have been **non-obvious** in view of the cited documents.¹

Applicants submit there is no *prima facie* case of obviousness, and it is courteously requested that the combination of WO ‘474, Orban, and Meheus et al. should be favorably reconsidered and withdrawn.

¹ Applicants do not rely on their arguments presented in their November 3, 2008 response.

WO '474 does not disclose "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10."

Applicants courteously submit the Office Action relies on a mistaken characterization of WO '474.

Contrary to the Office Action at page 2, **WO '474 does not state the composition includes "maltodextrin has a DE of 10-35 in an amount of 90-10%."**

WO '474 does not say the maltodextrin has a DE of 10 to 35.² Rather, WO '474 is quite specific in saying the DE is between those values, which excludes the end points. WO '474 at page 4, line 23. WO '474 teaches explicitly "[p]referably a maltodextrin having a DE between 12 and 20 is used." *Id.*

WO '474 refers to 80 to 20 parts of a carbohydrate source – and that is not weight percent. See WO '474, Abstract, page 4, line 5, as examples.

WO '474 instructs "from 80 to 20 parts of carbohydrate source comprising 10-90% processed starch and 90-0% maltodextrin," but that is not a composition that contains 90-10 w/w % maltodextrin.

Rather WO '474 is saying of the 80 to 20 parts of carbohydrate source, some 90 % to 10% may be a maltodextrin. In other words, WO '474 is saying, but only for the sake of argument, from 2 parts to 18 parts might be a maltodextrin. Still, "parts" is not "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10."

² Nor does WO '474 support the statement in the Office Action at page 4 ("the primary reference that already teaches maltodextrins upto [sic] a value of DE=10.")

Since WO '474 refers parts, it hardly teaches w/w/% of a maltodextrin having a DE of 3-10. Indeed, if other ingredients are present, from the general description in WO '474 it would not be feasible to ascertain amounts in w/w/% (e.g., wt.%) from the general description.

Even if WO '474, Table 1, is parsed, it clearly is not a disclosure or teaching directed to "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10."

Even when considering WO '474 at Table 1 at page 7, and assuming for the sake of argument the maltodextrin/modified wheat gluten ratio in Table 1, it could at best represent 14.4 wt. % of a maltodextrin of unspecified DE.

Even if there is potential overlap, WO '474 does not disclose the DE range of 3 to 10.

Furthermore, for the sake of argument, even assuming there is a mere paper overlap at DE=10, it would not anticipate the maltodextrin range of 3 to 10 in Applicants' claim 1, nor would it have suggested it. The Federal Circuit dismissed invalidity similar arguments based on an alleged overlap in *Atofina v. Great Lakes*, 78 U.S.P.Q.2d 1417, 1424 (Fed. Cir. 2006):

Further, we reject Great Lakes' argument that the district court's finding of anticipation was correct because JP 51-82206 discloses a preferred embodiment using a specific temperature range (a species) that anticipates the '514 patent's claim of a broader temperature range (a genus). JP 51-82206 discloses a preferred temperature range of 150 to 350 °C that slightly overlaps the temperature range claimed in the '514 patent. But that slightly overlapping range is not disclosed as such, i.e., as a species of the claimed generic range of 330 to 450 °C. Moreover, the disclosure of a range of 150 to 350 °C does not constitute a specific disclosure of the endpoints of that range, i.e., 150 °C and

350 °C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points. Thus, JP 51-82206 does not disclose a specific embodiment of the claimed temperature range.

Indeed, the cited WO '474 actually would not have led to the claimed range anyway. At page 4, lines 23 and 24, WO '474 discloses maltodextrins having a DE of between 10-35, and "preferably a maltodextrin having a DE between 12 and 20 is used." **See also** WO '474 at page 5, lines 9, 12, and 13. Thus, WO '474 provides explicit direction and incentive for a DE **greater than** 10.

Orban '677 would not have been combined with WO '474, and even if it was, the combination would not have taught Applicants' claimed inventions.

Orban neither discloses nor teaches Applicants' claim 1 elements, and therefore, even if combined with WO '474 the combination would not have led to Applicants' claimed inventions.

Applicants' claim 1 includes "a) from 20 w/w% to 70 w/w% cereal proteins"; "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10" and, for instance, "c) from 1 w/w% to 20 w/w% amino acids...", among other claim elements.

Orban does not disclose and would not have suggested "a) from 20 w/w% to 70 w/w% cereal proteins." Instead, Orban speaks in terms of specified vegetable proteins, but **does not refer to any cereal proteins.** Orban discloses "flour of soya, flour of peanuts, of ricinus, rapseed, cotton, sunflower, maize gluten, rice, etc." (Orban at column 1, lines 38-39), but this not a disclosure or teaching of "a) from 20 w/w% to 70 w/w% cereal proteins." The similar reference at column 2, lines 31-34 is likewise not a teaching of Applicants' element "a)." The reference to "broad beans, beans and certain types of yeasts" at column 2, lines 36-37 also does not teach Applicants' element "a)."

Orban does not disclose nor suggest "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10." A reference to 1 to 60 % carbohydrate is not a teaching of Applicant's claim element. The specific disclosure at column 3, line 24 et seq. with its long list of carbohydrates nowhere discloses or suggests maltodextrins, nor discloses a maltodextrin having a DE of 3 to 10.

Orban does not appear to disclose "c) from 1 w/w% to 20 w/w% amino acids..." Casual mention that amino acids may be present (column 4, lines 46-38) does not disclose nor teach of Applicants' claim element "c) from 1 w/w% to 20 w/w% amino acids..."

Applicants request the Examiner to reconsider the assertions made in the Office Action, including those at page 5, penultimate paragraph at page 6, second paragraph, inasmuch as they apparently lack evidentiary support.

Applicants request the Examiner to supply an Examiner's declaration with facts if the assertions are not withdrawn.

Therefore, even if Orban was combined with WO '474, Applicants' claimed inventions would not have been disclosed, nor would they have been suggested to a person of only ordinary skill in the art.

Meheus et al., would not have been combined with WO '474 and Orban '677, and even if it was, it would not have suggested the claimed inventions.

Meheus (U.S. 6,096,353) does not disclose nor would it have suggested "a) from 20 w/w% to 70 w/w% cereal proteins." Applicants also courteously suggest the Office Action may reflect a mis-understanding as to Meheus at column 4, line 40. Meheus refers to a mixture of two materials and that is not the same as a cereal protein per se. Meheus refers to 18-22 wt% of the mixture, and thus if one were hypothetically dissect Meheus to reach a protein in the mixture, the amount must be less than 18-22 Wt. %.

Applicants courteously invite attention to Meheus at test 1 and test 2 in Example 4, column 8, which apparently relate to 50/50 soya/wheat blend resulting in 7.5 wt. % and 11.7 wt. % of the blend. Thus, vivisectioning Meheus one might reach a protein in wt %, but it's only 3.75 wt. % and 5.85 wt.%. Again, Meheus does not disclose or teach Applicants' claim 1 element "a) from 20 w/w% to 70 w/w% cereal proteins."

Meheus does not and indeed could not teach Applicants claim 1 element "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10." Meheus makes no mention of maltodextrins. Therefore, even if WO '474, Orban and Meheus were combined, they would still not have taught Applicants' claim element "(b)."

Meheus does not disclose and would not have suggested Applicants claim 1 element "c) from 1 w/w% to 20 w/w% amino acids..." It is courteously submitted that the Office Action may rest on a misunderstanding of what Meheus does disclose. The Office Action refers to column 8, and from that derives a conclusion Meheus discloses amino acids in amounts overlapping Applicant's claim element "c) from 1 w/w% to 20 w/w% amino acids..." Applicants point out, however, that Meheus refers to ingredients in terms of kilograms per ton ("kg/ton"), not weight percent. So, when properly read, Meheus might be said for the sake of argument to contemplate 0.24 % amino acids ("test 1"), or 0.44% ("test 2"), but that **is not a teaching of Applicants' claim element element "c) from 1 w/w% to 20 w/w% amino acids..."**

Armbruster would not have been combined with WO '474, Orban '677, and Meheus, and even if it was, the combination would not have suggested Applicants' claimed inventions.

Applicants courteously request reconsideration and withdrawal of the Armbruster reference and any rejections based in whole or in part over said

reference. Applicants respectfully call attention to the Office Action at page 6, where it is said:

[A]pplicant's statement that the WO patent, Orban or Meheus et al. does not involve low DE starches, and Armbruster does not specifically mention calf milk replacement and the disclosure of Armbruster is not related to the WO patents, or Orban or Meheus et al, is correct and these are the reasons for rejection under 35 USC 103 not 35 USC 102.

Office Action, page 6, bottom paragraph. If "Armbruster [sic] is not related" to WO '474, or Orban or Meheus, Applicants believe that should have led to favorable reconsideration of the rejection.

Armbruster would not have been combined with the other references. Armbruster lists a number of theoretical uses (column 7, lines 50-64), but nowhere mentions the calf milk replacement, nor would it have led an ordinary worker to re-work the primary references as proposed in the Office Action.

The Office Action seems to mistakenly cite column 1, lines 20-26, of Armbruster, apparently for a disclosure of calf milk replacer. However, while Armbruster discloses what they meant by "food items" at column 1, lines 26-34, but none is related to the calf milk replacement of WO '474 or the compositions of Orban or Meheus et al. Therefore, other than 20/20 hindsight, Applicants respectfully submit there would have been no reason to combine Armbruster with WO '474, Orban '677 and Meheus.

Armbruster is also unrelated to the problem confronting Applicants, and therefore a person of ordinary skill in the art seeking to solve that problem (specification, page 7, as an example), would not have looked to Armbruster for guidance.

Moreover, for the sake of argument, *even if* Armbruster were combined with WO '474, Orban '677, and Mehues, which is not conceded, there would, for instance, have been no teaching of "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10."

Armbruster does not disclose Applicants' composition, and does not disclose Applicants' composition which has "b) from 25 w/w% to 70 w/w% maltodextrin" and does not disclose the claimed DE range ("maltodextrin having a DE of 3 to 10," claim 1).

The Armbruster patent simply makes low DE starches for clear and stable waxy starch hydrolysates. However, none of WO '474, Orban, or Meheus et al. involves low DE starches, e.g., maltodextrins with a DE of 3 to 10 (e.g., Applicants' claim 1), or maltodextrins with a DE of 5 (Applicants' claims 16 and 18).

Armbruster does not disclose and would not have suggested Applicants' composition with other elements. For example, Armbruster does not appear to disclose nor would it have suggested such a composition having "c) from 1 w/w% to 20 w/w% amino acids..." So, again, even if Armbruster were combined

with WO '474, Orban '677 and Meheus, the combination would not have taught an element in Applicants' claims.

Ernster has relevance only with impermissible hindsight.

Ernster apparently has theoretical relevance from its mention of a ring dryer, and that's the product of 20/20 hindsight.

The Ernster reference does not seem consistent with WO '474, Orban, and Meheus et al. Ernster would not have been combined with the other references. Ernster concerns "hydrolyzed proteinaceous milk solid[s]" (Abstract). At column 2, lines 10-13, Ernster refers to a hydrolyzed proteinaceous solid derived from milk which is low in fat content, but otherwise does not seem germane to the claimed invention.

The Branen extract would not have been combined with WO '474, Orban '677, Meheus, Armbruster and Ernster, and even if it was, the combination would not have suggested Applicants' claimed inventions.

The Branen extract was apparently cited in the Office Action because it mentions low DE maltodextrins. However, the extract does not disclose, nor does it suggest Applicants' claim 1 composition with its elements a) through d), and it specifically does not appear to disclose or suggest such a composition with "b) from 25 w/w% to 70 w/w% maltodextrin having a DE of 3 to 10."